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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,363	05/25/2000	Barbara P. Wallner	I0248/7012 (ERG/MAT)	6092

7590 07/16/2003

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,363

Applicant(s)

WALLNER ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-19, 31 and 36-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38, 39, 58, 60-62, 64 and 65 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11-19, 31, 36, 37, 40-54, 56, 59, 63, 67, 68 and 74-81 is/are rejected.
- 7) ☒ Claim(s) 3-8, 55, 57, 66 and 69-73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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1. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. Claims 1, 19, 36, and 37 recite a new formula that was not explicitly recited in the specification as originally filed and embraces numerous compounds not embraced by the original claims. For example, as currently claimed, peptides comprising as many as 22 amino acid residues are embraced, whereas Formula II as recited in the original disclosure embraces only as many as twelve amino acid residues. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

The supplemental oath or declaration referred to in Applicants' response has not yet been received. The supplemental oath or declaration can be filed at any time up to three months after the mailing of a Notice of Allowance.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52, 56, 59, and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure of the use of prednisone as an anti-cancer agent. The examiner has reviewed pages 23-28 of the specification, pointed to by Applicants as support for the new claim language, but could not find any mention of prednisone.

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3. Claims 52, 56, 59, and 63 are objected to because of the following informalities: At claim 52, lines 1-2, the phrase "wherein the anti-cancer compound is" is repeated. At claim 52, line 10 (and at a similar location in claims 56, 59, and 63), "Porfimer" is misspelled. At claim 52, line 10 (and at a similar location in claims 56, 59, and 63), "Procarbazine" is misspelled. Claim 52, line 10 (and at similar locations in claims 56, 59, and 63) recites the registered trademark "Taxol". However, the trademark is not appropriately identified as a registered trademark (see MPEP 2173.05(u)), and in any event is redundant to "Paclitaxel" which is recited in line 9. It is suggested that "Taxol" be deleted from the claim. Appropriate correction is required.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 11-19, 31, 36, 37, 40-51, 53, 54, 67, 68, and 74-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 09/744,658 in view of O'Reilly et al or Brooks et al. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '658 application claims treating medical conditions including angiogenesis, neoplasm, tumors, and cancer by administering a DPP-IV inhibitor, preferably Val-boroPro. See

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claims 10, 13, and 20. The '658 application does not claim combining its DPP-IV inhibitors with antiangiogenic or anti-cancer compounds, does not claim combining its DPP-IV inhibitor administration with surgical treatment, and does not claim the subjects being treated for angiogenesis, neoplasm, tumors, or cancer as being otherwise free of symptoms calling for hemopoietic stimulation, as having normal hemopoietic activity, or as being HIV negative. O'Reilly et al (see, e.g., column 14, lines 20-27) and Brooks et al (see, e.g., column 8, lines 13-25) disclose that it is known to combine surgical, chemotherapeutical, and anti-angiogenic treatments in treating tumors. It would have been obvious to one of ordinary skill to combine the angiogenesis, neoplasm, tumor and cancer treatment claimed in the '658 application with other known methods of treating angiogenesis, neoplasm, tumors, and cancer, including surgery or treatment with other anti-tumor compounds including angiogenesis inhibitors, because O'Reilly et al and Brooks et al show that it is routine in the cancer therapy arts to combine treatments in order to optimize treatment of the cancer. It would have been obvious to one of ordinary skill in the art to treat angiogenesis, neoplasm, tumors, and cancer according to the claimed method of the '658 application in any subject, including those patients recited in instant claims 11, 16, and 17, because it is desirable to treat angiogenesis, neoplasm, tumors, and cancer in any patient in which the conditions are found, and because the hemopoietic activity or HIV status of such a patient would not have been expected adversely to affect the patient's ability to be treated in the claimed method of the '658 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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5. Applicant's arguments filed June 13, 2003 have been fully considered but they are not persuasive.

The provisional obviousness-type double patenting rejection over copending application 09/744,658 is maintained, but can be withdrawn consistent with the procedures of MPEP 822.01 once the claims are otherwise in condition for allowance.

The showing of common ownership at the time the invention was made satisfies the requirement set forth in paragraph 5 of the previous Office action and overcomes the provisional obviousness rejection set forth in paragraph 8 of the same action.

6. Claims 38, 39, 58, 60-62, 64, and 65 are allowed. Claims 3-8, 55, 57, 66, and 69-73 would be allowable if rewritten to overcome the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 59 and 63 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, and the claim objections set forth in this Office action. Claims 52 and 56 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, and the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

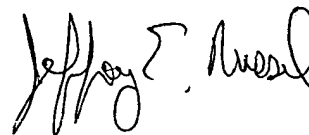
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 14, 2003